

REMARKS/ARGUMENTS

Claims 1-17 and 27-29 were pending and stand substantively rejected. Claims 18-26 and 30-36 are canceled. In this Amendment, claims 1, 17, and 27 are amended, and new claim 37 is added. Reconsideration is respectfully requested.

Claim Amendments

Amended claims 1, 17, and 27 incorporate elements from presently pending claims 7, 10, and 13. Support for the amendment to claim 6 can be found in the specification at, for example, paragraph [0155]. Support for new claim 37 can be found in the specification at, for example, paragraph [0077]. No new matter is introduced.

First Rejection Under 35 U.S.C. §112

Claims 1-17 and 27-29 were rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. This rejection is traversed.

Agonist

The Office Action alleges that the specification does not reasonably provide enablement for administration of agonists. Amended independent claims 1, 17, and 27 do not recite the term "agonist".

Body Weight

The Office Action alleges that the specification does not provide working examples of decreasing body weight or preventing an increase in body weight, as discussed in presently pending claims 1 and 3, respectively. Moreover, the Office Action states that at the time of invention, the skilled artisan would have recognized that hypocretins increase food intake.

Working Example Not Required

According to MPEP 2164.02, compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An applicant need not have actually reduced the invention to practice prior to filing. The specification need not contain an example if the claimed subject matter is otherwise disclosed in such manner that the artisan will be able to practice it without an undue amount of experimentation.

The Artisan Would Not Conclude that Hypocretin Increases Food Intake

Haynes (1999) and Preti (2002) may suggest that in some circumstances hypocretin may increase food intake, however others report that evidence for a role for hypocretin in food intake regulation is inconsistent. See Abstract, Siegel, "Hypocretin (Orexin): Role in Normal Behavior and Neuropathology, Ann. Rev. Psychol., 55:125-148 (2004). Relatedly, as Siegel explains at page 140, hypocretin knockout animals are not emaciated, contrary to what would be predicted by the hypocretin-feeding hypothesis. Hence, the allegation that the skilled artisan would have recognized hypocretins increase food intake is improperly based, and cannot support a rejection of the pending claims.

Regardless, food intake is not the sole determinant of body weight, and thus it is improper to assume that an increase in food intake must necessarily lead to an increase in body weight.

According to MPEP 2164, enablement requires that the specification describe how to make and how to use the claimed subject matter. In the instant case, the specification provides ample disclosure for how to practice the presently claimed methods. For example, paragraphs [0110]-[0142] describe a thorough description of treatment regimes and methods of administration. Based on the above, the presently claimed methods are disclosed in such manner that the artisan is enabled to make and use the claimed methods without an undue amount of experimentation. As noted in MPEP 2164, to comply with 35 U.S.C. 112, first paragraph, it is *not* necessary to enable the artisan to make and use a perfected, commercially viable embodiment.

Second Rejection Under 35 U.S.C. §112

Claims 1-17 and 27-29 were rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking compliance with the written description requirement. This rejection is traversed.

Hypocretin

The Office Action alleges that the term "hypocretin" lacks written description. Amended independent claims 1, 17, and 27 recite the terms "hypocretin-1 or hypocretin 2".

Agonist

The Office Action alleges that the specification does not reasonably provide enablement for administration of agonists for preventing or treating excess body weight. Amended independent claims 1, 17, and 27 do not recite the term "agonist". Withdrawal of this rejection is respectfully requested.

Third Rejection Under 35 U.S.C. §112

Claims 1-17 and 27-29 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. This rejection is traversed.

The Office Action alleges that the term "hypocretin" is ambiguous. Amended independent claims 1, 17, and 27 recite the terms "hypocretin-1 or hypocretin 2". Withdrawal of this rejection is respectfully requested.

First Rejection Under 35 U.S.C. §102

Claims 1, 14-17, and 27-29 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kiyaschchenko, Journal of Neurophysiology 85:2008-2016 (2001). This rejection is traversed.

In amended independent claims 1, 17, and 27, the individual is overweight, suffers from a weight disorder, or suffers from obesity. These elements are recited in presently pending claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are not anticipated.

Second Rejection Under 35 U.S.C. §102

Claims 1, 4-6, 14-17, and 27-28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Haynes, Peptides 20:1099-1105 (1999). This rejection is traversed.

In amended independent claims 1, 17, and 27, the individual is overweight, suffers from a weight disorder, or suffers from obesity. These elements are recited in presently pending claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are not anticipated.

Third Rejection Under 35 U.S.C. §102

Claims 1, 6, 14-17, and 27-28 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by USPN 7,112,566 to Siegel. This rejection is traversed.

In amended independent claims 1, 17, and 27, the individual is overweight, suffers from a weight disorder, or suffers from obesity. These elements are recited in presently pending claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are not anticipated.

Fourth Rejection Under 35 U.S.C. §102

Claims 1, 6, 14-17, and 27-28 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by USPN 7,335,640 to Siegel. This rejection is traversed.

In amended independent claims 1, 17, and 27, the individual is overweight, suffers from a weight disorder, or suffers from obesity. These elements are recited in presently pending claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are not anticipated.

Fifth Rejection Under 35 U.S.C. §102

Claims 1, 4-6, 14-17, and 27-28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Taheri "The Role of Orexins in the Regulation of Appetite, Sleep and Arousal, Abstract Number Y16 presented at Spring Meeting, Royal College of Physicians, London, on June 1, 2001. This rejection is traversed.

In amended independent claims 1, 17, and 27, the individual is overweight, suffers from a weight disorder, or suffers from obesity. These elements are recited in presently pending claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are not anticipated.

First Double Patenting Rejection

Claims 1, 14, 15, 17, and 27-28 were rejected on the ground of nonstatutory obviousness-type double patenting over USPNs 7,112,566 and 7,335,640. Amended independent claims 1, 17, and 27 incorporate elements from claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are patentable over the cited patents. Withdrawal of this rejection is respectfully requested.

Second Double Patenting Rejection

Claims 1, 14, 15, 17, and 27-28 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over USSN 11/937,891. Amended independent claims 1, 17, and 27 incorporate elements from claims 7, 10, and 13, which are not included in the rejection. Hence, amended claims 1, 17, and 27 are patentable over the cited patents. Withdrawal of this rejection is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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